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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,644	SUNG ET AL.	
	Examiner	Art Unit	
	AGNIESZKA BOESEN	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-17,19-35 and 38-40* is/are pending in the application.

4a) Of the above claim(s) *30-35 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-17,19-29,38 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/11/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 11, 2008 has been entered.

Claims 1, 6, 16, 21, 30, 33-35 have been amended. Claims 1, 2, 4-17, 19-29, 38 and 39 are under examination in the present Office action.

Election/Restriction

Newly submitted claims 38 and 39 are directed to the same invention as the elected invention of group I drawn to the DNA vaccine, and therefore claims 38 and 39 are examined in the present Office Action. New claim 40, drawn to a method of enhancing protective immunity is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The newly submitted claims are drawn to two different inventions:

I. Claims 1, 2, 4-17, 19-29, 38 and 39, drawn to a DNA vaccine, classified in class 424, subclass 218.1.

II. Claims 30-35 and 40, drawn to drawn to a method of enhancing protective immunity to hepatitis C virus, classified in class 514, subclass 44.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

on the merits. The invention of the above group I has been examined on the merits in the Office action of 5/24/2007 and 3/14/2008, and therefore claims 1, 2, 4-17, 19-29, 38 and 39, directed to the invention of group I are presently examined. Accordingly, claims 30-35 and new claim 40 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. It is noted that the method claims can be rejoined once the product claims are indicated allowable. Product claims are presently rejected as discussed below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection of claims 1, 2, 4-17, 19-29 and new claims 38 and 39 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement **is maintained as a scope of enablement rejection.**

Claims 1, 2, 4-17, 19-29, 38 and 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition for inducing immune responses to treat HCV infection in HCV infected subjects, does not reasonably provide enablement for a vaccine (that prevents or protects against HCV infection).

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicant's arguments have been fully considered but fail to persuade. Applicants argue that there are no claims currently under prosecution that claim a method of treating or preventing HCV and that the withdrawn claims are drawn to methods of enhancing protective immunity to HCV. Applicants argue that that the present patent application clearly teaches how to use the claimed vaccine to enhance protective immunity and thus limit or inhibit the development of chronic infection.

In response to Applicant's arguments the Office acknowledges that the present specification provides working examples showing induction of immune responses due to immunization of chimpanzees with the recombinant adenovirus constructs comprising HCV proteins. It is also acknowledged that Applicants conducted challenge experiments in immunized chimpanzees. Working examples 12 and 16 discuss immunization and challenge experiments in chimpanzees. Example 12 refers to Figure 15 in the drawings, and Table 1. Figure 15 shows vaccination and challenge schedule and Table 1 provides general information with regard to chimpanzee's age and exposure to HBV and HCV. Example 16 discusses quantification of HCV in challenged chimpanzees using quantitative PCR. Figure 19 shows the results of the quantitative PCR. However, the results of the HCV measurement in Figure 19 show detectable levels of HCV, at two weeks post challenge in chimpanzee designated as "400" and in chimpanzees "397" and "402". The results show even higher levels of HCV at four weeks post challenge as compared to two weeks post challenge, see" chimpanzee 381, 397, and 402. Only one chimpanzee 393 showed undetectable levels of HCV at two and four weeks post challenge. Thus Applicant's experimental results clearly indicate that the vaccine composition of the present invention was not effective in preventing HCV infection in chimpanzees.

While the compositions of the invention are effective in inducing HCV specific cellular immune responses and while it would have been predictable that the compositions could be used to treat HCV infection in HCV infected patients, it would have been rather unpredictable to conclude that the present compositions could be used as preventative or protective vaccines.

Examiner has reviewed the references discussing the state of the art with regard to the HCV vaccines, provided by Applicants on 9/11/2008. Examiner acknowledges that the researches developing vaccines against HCV focus their strategies to limit chronic infection rather than to prevent infection itself, as argued by Applicants. However the term "vaccine" recited in the present claims is not limited to the therapeutic vaccines that are aimed at treating chronic HCV infection in HCV infected patients, but broadly encompasses the preventative and protective vaccines. Additionally, the present specification does not define the claimed DNA vaccine as a vaccine that is limited for the therapeutic use in patients infected with HCV. The specification defines the DNA vaccine as a plasmid containing genes that work as antigens (see [0020]). Furthermore, the specification contemplates vaccines used for protection against HCV infection as well as treatment of HCV (see [0017-0019).

[0017] In order to achieve other object of the invention, the present invention provides a vaccine administrating method characterized by enhancing the protective immunity to HCV by boosting with the above adenovirus vaccine after priming with the DNA vaccine 2-5 times.

[0018] The present invention also provides a method to enhance the protective immunity to HCV by increasing CD4+ Th1 immune response by boosting with a recombinant adenovirus vaccine after priming with a DNA vaccine.

[0019] The present invention further provides a method for the prevention and the treatment of hepatitis C, which is characterized by boosting with a recombinant adenovirus vaccine after priming with a DNA vaccine.

[0020] The term "DNA vaccine" herein means a plasmid containing a gene coding a protein that works as an antigen or a substance containing the said plasmid and pharmaceutical components that are generally added for the vaccine preparation.

The reference by Lechman et al. (Seminars in Liver Disease, 2000) submitted by Applicants discusses the obstacles to developing protective HCV vaccines. Lechman et al. also discusses the development of therapeutic HCV vaccines. As of today a preventative vaccine against HCV does not exists.

In conclusion, in view of the teachings in the art and the working examples provided in the specification it is the Office's position that the Applicants have not provided sufficient enablement for the claimed vaccines. Thus in view of the above the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Rejection of claims 1, 2, 6, 16, 21 and new claims 38 and 39 under 35 U.S.C. 102(b) as being anticipated by Saito et al. (US Patent 5,731,172) **is maintained.**

Rejection of claims 1, 2, 6 and new claim 38 under 35 U.S.C. 102(e) as being anticipated by Tang et al. (US 2004/0166488 A1) **is maintained.**

Applicant's arguments have been fully considered but fail to persuade. Applicants amended the claims to recite "consisting essentially of" with regard to the components of each plasmid. Applicants argue that the first, second and third plasmid of claims 1 and 16 cannot contain the additional elements described by Saito et al. and Tang et al.

In response to Applicants arguments the Office notes that the term "consisting essentially of" is construed as "comprising" absent a clear indication in the specification of what the term "consisting essentially of" is intended to encompass (see MPEP 2111.03). Thus the claims, as amended read on a DNA vector comprising DNA encoding E1, E2, NS3, NS4 and NS5 proteins. Because both, the Saito's and Tang's constructs comprise DNA encoding E1, E2, NS3, NS4 and NS5 proteins, Tang and Saito anticipate the present claims.

With regard to the new claims 38 and 39, the claims recite the same limitations as claims 1 and 16 respectively, except for the limitation "wherein the DNA vaccine enhances cytotoxic T lymphocyte response in a person immunized with the DNA vaccine." Claims 38 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Saito et al. (US Patent 5,731,172) and Tang et al. (US 2004/0166488 A1) as discussed in the Office Action of 5/24/2007. The limitation of "wherein the DNA vaccine enhances cytotoxic T lymphocyte response in a person immunized with the DNA vaccine." is viewed as an inherent property of the compositions disclosed by Tang et al. and o et al. Thus in view of the above the rejections are maintained.

Conclusion

No claim is allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art

of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AGNIESZKA BOESEN whose telephone number is (571)272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen/

Examiner, Art Unit 1648

/Bruce Campell/

Supervisory Patent Examiner, Art Unit 1648